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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,044	08/11/2001	Jon M. Bishay	33734-8001US2	7172

7590

12/03/2003

BLANK, ROME, LLP
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WASHINGTON, DC 20037

EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 12/03/2003

121

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/928,044

Applicant(s)

BISHAY, JON M.

Examiner

George R Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) 31-34 and 42-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 and 35-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2-5. 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Claims 31-34 and 42-72 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

Information Disclosure Statement

The information disclosure statement filed 8/5/02 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Several of the references listed were not in either parent case. Due to the numerous references, it is suggested to have someone hand carrier the references to the examiner.

The information disclosure statement filed 8/5/02 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because several of the references did not contain a date of publication. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-30 and 35-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 35, “supporting a percutaneous electrode” is vague and is inferentially including the electrode. The electrode has not been positively recited, but the housing is claiming a positive connection (not a functional connection) to the electrode. It is unclear if applicant is intending to positively claim the electrode. The examiner has interpreted the claim as including the percutaneous electrode since the claims contain connection to the electrode and since dependent claims 8 and 39 state that the electrode is positioned in the housing. It is suggested to positively recite the electrode.

In claims 1, 16, 17, 18, 25, and 35, the claims are vague because they sound as if they are claiming a positive connection to the body (“to penetrate a skin”, “and attach to the skin”, etc). Apparatus claims cannot claim connection to the body. It is suggested to use language similar to “adapted to be”, “configured to be”, or “for ...”.

In claims 1, 18, 25, and 35, “a releasable bond” is inferentially included.

In claim 7, “the first” should be deleted.

In claim 8, “the adhesive member” lacks antecedent basis.

In claim 12, “the adhesive member” and “the adhesive surface” lack antecedent basis.

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In claim 15, the claim is incomplete for omitting essential structural cooperative relationship between elements. The compressible material is not connected to any of the first or second portion or the releasable bond and the claim is just a listing of parts.

In claim 16, "further comprising...electrode" should be deleted since claim 1 already contains the electrode.

In claim 39, "the adhesive member" lacks antecedent basis ("the adhesive lower surface").

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10, 11, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Farrar et al (4281659). Farrar shows the percutaneous electrode, 15, housing, 10 or 30, first portion, 20, second portion, 2, releasable bond, 16 cooperating with hole, the tab, other reference numeral 16, and stop as taper 4b.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13-15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Farrar et al. Farrar discloses the use of adhesive, foam pad (compressible material), and cover sheet on the second portion in figures 15 and 16.

In the alternative, Farrar discloses the claimed invention using an adhesive, foam pad, and cover sheet attached to the second portion in a non-fetal use but does not show the rest of the connections to the housing and first portion and therefore, Farrar does not disclose the use of an adhesive, compressible material, and cover sheet on the second portion or attachment member when connected to the housing and first portion. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrode system as taught by Farrar, with an adhesive, compressible material, and cover sheet on the second portion or attachment member since it was known in the art that electrode systems use an adhesive, compressible material, and cover sheet on the portion engaging the skin (the second portion) to allow the portion to firmly attach to the skin and remain in place, to allow the engaging portion to be comfortably attached to the skin, and to prevent the adhesive from losing its adhesive properties prior to use.

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Allowable Subject Matter

Claims 18-30 and 35-42 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.


Claims 2-9 and 17 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703 306-4520.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1148.


George R Evanisko
Primary Examiner
Art Unit 3762

11/30/3

GRE
November 30, 2003